



CONSULTATION ON THE
IMPLEMENTATION OF
WITHDRAWAL OF PAYMENTS
TO DONORS

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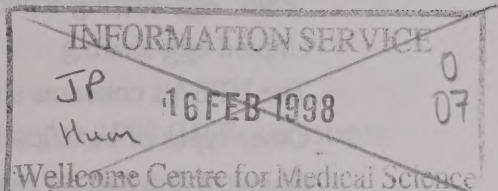


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CONSULTATION ON THE IMPLEMENTATION OF WITHDRAWAL OF PAYMENTS TO DONORS

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PART 1. INTRODUCTION

Background

1.1 Section 12(e) of the Human Fertilisation and Embryology Act 1990 (HFE Act) states:

“that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions”.

1.2 HFEA Directions¹ currently allow clinics who were paying donors before 1 August 1991 to continue to do so up to a limit of £15 per donation plus reasonable expenses. Clinics who were not making payments to donors on that date are allowed only to pay donors their reasonable expenses. This arrangement was intended to maintain the status quo without allowing payments to increase. This policy was publicly stated in the HFEA's second Annual Report²:

“When the Authority first took up its powers, directions were issued to limit the value of money or other benefits which may be given to donors. This was in order to maintain existing practice during the transitional period but the intention, in the longer term, was that payment should eventually be phased out. The Authority will need to review the ethical issues surrounding this matter and assess the possible effects of phasing out payment to donors.”

1.3 In 1993 the HFEA commissioned two pieces of research on the subject from Rachel Cook and Susan Golombok³. This was followed by a conference in 1995. Having considered and discussed all the material presented to it, the HFEA in July 1996 announced its decision that, in principle, it was opposed to payments being made for gamete donation. The HFEA's intention was then, and remains, that payments to donors should be phased out in such a way as to minimise any adverse effects, particularly any reduction in the supply of sperm donors. The HFEA set up a Working Group to consider the possible impact of this policy on gamete donor recruitment and the ways in which the supply of male donors could be maintained and the number of female donors increased. This consultation document is based on that Working Group's report.

¹ HFEA, Giving and receiving money or other benefits in respect of any supply of gametes or embryos, General Directions, D.1996/1, Manual for Centres, Version 2.2, March 1996.

² HFEA, Second Annual Report, 1993, page 29.

³ Cook, R and Golombok, S. A survey of semen donation: Phase II - the view of the donors. *Human Reproduction*. 1995; 10, 951-959; Golombok, S and Cook, R. A survey of semen donation: Phase I - the view of UK licensed centres. *Human Reproduction*. 1994; 9, 882-888.

The reasoning behind the HFEA's decision

1.4 In developing its policy the HFEA took into account how payment might affect the values associated with donation. For example, whether donated gametes should be perceived as a gift or a commodity and whether payment could affect this perception. The HFEA also considered whether payment might be given for other aspects of the donation rather than for the gametes themselves, and, if so, whether payment for these could be clearly separated. In addition, the HFEA was concerned about how the values attributed to donated gametes might affect the social context in which the resulting children were born.

1.5 In reaching its decision two major principles emerged. These were that:

- fully informed consent, free from any inducement and pressure, is fundamental to gamete donation; and
- the potential for human life inherent in a donation made with the specific intent of producing children should be respected.

1.6 HFEA Members were concerned that payments to sperm or egg donors could jeopardise these principles, and agreed that it was possible for a donor to be financially induced. If this were the case, the inducement might compromise the ability of the donor to consider fully the implications of their donation. There were fears that a donor might later come to regret their decision to donate. While Members accepted that payment did not necessarily, or inevitably, mean that donors had been financially induced, they agreed that the risk of that happening was unacceptable. Although Members also recognised that fertility treatment should be made as freely available as possible, a principle which might be jeopardised by the removal of payment, they concluded that a system of non-payment was desirable in order to promote best practice and protect the interests of donors, recipients and children.

1.7 The HFEA also considered other forms of donation, in particular blood and organ donation. Members agreed that, as gamete donation may result in the creation of new life, there were more serious consequences flowing from this type of donation than with other kinds. Payment might lead to donors being exploited, and might also result in the children so produced being perceived as commodities. In the UK blood and organ donors do not receive payment, and payments for children who are being adopted are forbidden. In this context the HFEA concluded that payments to gamete donors was contrary to the accepted national ethos. This general conclusion is also supported by the Nuffield Council on Bioethics in its report, "Human Tissue: Ethical and Legal Issues"⁴.

⁴ Nuffield Council on Bioethics. Human Tissue: Ethical and Legal Issues. April 1995.

1.8 The HFEA also considered the payment of compensation to donors on the basis of the risks or discomfort undergone by them in making their donation. In connection with this the HFEA considered the implementation of a tariff system⁵. The HFEA concluded that the tariff system used in medical trials was not an appropriate model for a number of reasons. Volunteers in medical trials are involved in advancing medical science in a general sense rather than in giving their genetic material for the treatment of others. The context in which such payment is made therefore appeared to the HFEA to be very different. In addition, a recommendation made by a Royal College of Physicians Working Group⁶ that payments in clinical trials should not be associated with any level of risk, highlighted the difficulty in establishing a sound basis for calculating compensation. The discomfort associated with a donation seemed even harder to quantify because of the possible range of individual responses. An additional problem identified with the payment of compensation was that the payment would be known about in advance of the donation. As a result, even if the payment were intended to compensate only for inconvenience experienced, it would be impossible in practice to introduce such a system that did not also have the potential to act as a financial inducement.

The HFEA's conclusions

1.9 The HFEA concluded that a gamete donation should be a gift, freely and voluntarily given with informed consent, and that payments to donors should be phased out. Having said that, the HFEA did not wish donors to lose out financially by donating, and agreed that a system of expenses payments should be established which was financially neutral for the donor. Under this system donors would be reimbursed only for verified, necessary and consequential expenses incurred directly as a result of making their donation. This decision took into account, as fully as possible, the various interests of donors, patients and children conceived through the use of donated gametes.

1.10 The HFEA also considered the giving of benefits-in-kind in exchange for donation. Having reached the conclusion that there should be a move away from payment, the HFEA compared benefits-in-kind with payment to see whether any clear distinctions could be made between the two. It was felt that benefits-in-kind would be seen as payment in a different form, and that therefore the same conclusion should be reached. It follows that an arrangement involving benefits-in-kind, such as an egg-sharing scheme in which a couple receives treatment at a reduced charge in exchange for donating eggs (paid egg-sharing), ought also to be phased out.

⁵ Evans, D. Procuring gametes for research and therapy. *J. Med. Ethics.* 1995; **21**, 261-264.

⁶ Royal College of Physicians Working Group. Report: Research on Healthy Volunteers, 1986.

PART 2.

CONSEQUENCES OF REMOVING PAYMENTS TO DONORS

Sperm donation

2.1 A survey of the published literature on the attitudes of current UK sperm donors to donation suggests that stopping payment would result in a significant decrease in the number of donors recruited. This is because, as several studies indicate, for a majority of current donors payment is a motivational factor⁷. This view is shared by many professionals working in centres.

2.2 There is also evidence that students account for the majority of sperm donors who are currently recruited⁸. The attitudes of current sperm donors are not, however, necessarily representative of those of the wider male population. Published studies of non-donors indicate that their attitudes are different⁹, and this evidence suggests that, by targeting different groups, it may be possible to attract donors without offering payment. One published study showed that this approach could have some success¹⁰. The unpaid donors recruited had different attitudes towards donation compared with students recruited with payment. However, it is accepted that there is a paucity of evidence, and it is unclear from published material how many donors could actually be recruited without payment. What is certain is that a substantial change in clinics' approach to donor recruitment is required in order to make a policy of non-payment successful in terms of the number of donors recruited. It has been suggested that an "esteem" based approach, showing more appreciation and gratitude towards donors rather than rewarding them financially, would be successful in recruiting non-paid donors¹¹.

2.3 A number of consequences might follow from a decline in the supply of sperm donors. Couples may chose to seek unregulated donor insemination which could place both patients and the child at greater risk because of the use of an unscreened, and possibly uninformed, donor. Insemination by a donor outside a licensed clinic also raises problems of legal parentage. Alternatively couples might seek treatment abroad in preference to the increased waiting times that would result. It has also been suggested that the cost of Donor Insemination (DI) would rise if the number of donors declined. In addition, it has been argued

⁷ Cook and Golombok, op. cit., (3); Lui, S C, Weaver, S M, Robinson, J et al. A survey of semen donor attitudes. *Human Reproduction*. 1995; **10**, 234-238; Lui, S C and Weaver, S M. Attitudes and motives of semen donors and non-donors. *Human Reproduction*. 1996; **11**, 2061-2066.

⁸ Golombok and Cook, op. cit., (3); Monteiro, E, Spencer, R, Kinghorn, G, Barratt, Cooke, S, Cooke, I. Sexually transmitted disease in potential semen donors. *BMJ*. 1987; **295**, 418.

⁹ Lui and Weaver, op. cit., (7); Daniels, K R, Curson, R and Lewis, G M Semen donor recruitment: a study of donors in two clinics. *Human Reproduction*. 1996; **11**, 746-751.

¹⁰ Daniels, Curson, and Lewis, ibid.

¹¹ Daniels, K R and Hall, D J Semen donor recruitment strategies - a non-payment based approach. *Human Reproduction*. 1997; **12**, 2330-2335.

that there would be a temptation to consider accepting donors with lower sperm counts, progressive motility or sperm morphology which might adversely affect patients because of a reduced live birth rate.

2.4 Changing to a system of non-payment might also result in a higher proportion of sperm donors over the age of 35 or 40 being recruited. It has been suggested that the incidence of serious non-chromosomal birth defects, especially those arising from new autosomal mutations, increases with paternal age¹². Therefore, if the average age of sperm donors rose, there might be an increased risk to patients and potential children resulting from treatment. However, following a consultation with clinics, the HFEA recently agreed not to lower the upper age limit for sperm donors because the evidence available was inconclusive.

2.5 However, a decline in the number of donors should be viewed in context. An additional factor which cannot be predicted is the effect that new technologies, such as Intra Cytoplasmic Sperm Injection (ICSI), may have on the demand for donated sperm. Over the last four years for which data are available the number of DI cycles per year has dropped from 26,000 (1992) to 17,857 (1995)¹³. If this trend were to continue a reduced supply of donors would have less effect on service provision.

Egg donation

2.6 Published and unpublished evidence on egg donors suggests that payment is not a motivational factor for women who donate¹⁴. This indicates that the current supply of egg donors will not decrease simply as a result of payment being withdrawn. It is likely that, in any case, the majority of egg donors do not receive financial payment at present either because they do not wish to receive payment even when offered or because payment is not available as the clinic did not have an ongoing egg donation programme as of 1 August 1991.

2.7 The issues surrounding egg donation are different to those surrounding sperm donation as there is presently a shortage of egg donors with waiting lists for treatment at some clinics. There have been various campaigns to recruit egg donors which have met with some success. However, some commentators have criticised the use of advertising fearing that women will be pressurised into egg donation through guilt rather than altruism¹⁵. Advertising for donors may also add to the cost of treatment with donated eggs.

¹² Bordson, B L, Leornado, V S. The appropriate upper age limit for semen donors: a review of the genetic effects of paternal age. *Fertility and Sterility*. 1991; **56**, 397-401.

¹³ HFEA, Third Annual Report, 1994; HFEA, Sixth Annual Report, 1997.

¹⁴ Abdalla, H I. A national oocyte donation society is needed. *Human Reproduction*. 1996; **11**, 2355-2356. Kirkland, A, Power, M, Burton, G, Baber, R, Studd, J and Abdalla, H. Comparison of attitudes of donors and recipients to oocyte donation. *Human Reproduction*. 1992; **7**, 355-357.; Cook and Golombok, op. cit. (3).

¹⁵ Ahuja, K K, and Simons, E G. Anonymous egg donation and dignity, *Human Reproduction*. 1996; **11**, 1151-1154.

2.8 In addition to the issues surrounding the recruitment of egg donors, it is possible that developments in the freezing of eggs or the *in vitro* maturation of immature oocytes may lead to an improvement in the supply of donated eggs. Advances in cryopreservation technology for mouse oocytes mean that post-thaw survival and development of eggs is in the same range as for control eggs. The situation in humans is less advanced, but some progress is being made. The capacity to freeze eggs successfully could have a major impact on supply since egg donors would be able to store their eggs unfertilised and recipients would be able to thaw and fertilise only as many as they required at any one time thus enabling more recipients to be treated by each egg donor. In addition, couples undergoing *in vitro* fertilisation (IVF) treatment might elect to store unfertilised eggs in preference to embryos and then consent to their donation when their own families were complete.

PART 3.

CONTEXT AND CULTURE

Introduction

3.1 The different procedures involved in egg and sperm donation, the historical development of the techniques involved and the associated cultural values are all important factors in how male and female donors are recruited. Infertility has long been seen as a female problem with male infertility often denied or ignored. Further, there was, and still is, a common tendency to confuse fertility and potency in men. This has implications for sperm donation as male infertility is still seen as a taboo subject. In addition, a man must masturbate in order to donate. Masturbation is not only taboo, but the link between sexual pleasure and the act of donation harms the concept of the donation as a gift. In contrast, egg donation is more clearly separated from a woman's sexuality, and the gift nature of the donation has, as a result, become more prominent. In addition, men are generally less comfortable than women in talking explicitly about issues of fertility and sexuality. The fact that egg donation developed as a technique during the 1980s may also have encouraged a more open approach. DI was first introduced as clinical practice in the 1930s, and attitudes to sperm donor recruitment may reflect this longer history.

3.2 Despite the historical and cultural background to sperm donation, attitudes to DI have changed over the years. The DI child was regarded as illegitimate until the Family Law Act 1987 which recognised the husband as the legitimate father if he consented to the treatment. The HFE Act clarified the position further in that, where treatment services are being provided to a couple together, the male partner is considered the legal father. The other major change is the statutory requirement for the HFEA to keep a register of all treatment cycles so that the genetic origins of children born as a result of the use of donated gametes is on record. Donors are also invited to provide non-identifying information about themselves which may be given to the child, but how this will be put into practice has yet to be decided. The public discussion surrounding the development and application of this legislation has reduced the secrecy and ignorance about sperm donation. Nonetheless, strong taboos remain. Continuing public education about these issues is highly desirable.

3.3 It is likely that cultural change will need to accompany a move towards non-payment. It has been suggested that receiving payment neutralises the donation by rewarding the donor and removing any feeling of indebtedness on the recipients' part¹⁶. The HFEA agrees that this perception reinforces the secrecy that traditionally surrounds DI and the negative cultural values placed on male infertility and donor insemination.

¹⁶ Nijs, P, Steeno, O and Steppe, A, Evaluation of AID donors: medical and psychological aspects. A preliminary report. *Human Artificial Insemination*. Eds David, G and Price, W S, Plenum Press, New York. 1980.

Comparison with other countries

3.4 A comparison with other countries shows that cultural values surrounding fertility and gamete donation are not consistent world-wide, and that cultural factors play an important role in determining which recruitment strategies will be most effective. In New Zealand, for example, sperm donation is dealt with more openly and this results in a proportion of identifiable donors being recruited¹⁷.

3.5 Outside the UK there is a wide range of regulation in place. Payments to donors are made in several countries, such as America and Australia, but where changes are occurring they are usually in favour of non-payment. For example, France passed legislation in 1994 prohibiting payment for gamete donation (see Annex A).

3.6 Within Europe the issue of gamete donation is also being considered. A Council of Europe Report¹⁸ on human artificial reproduction prepared by the Ad Hoc Committee of Experts on Progress in the Bio-Medical Sciences sets out a series of principles as conditions for the use of artificial procreation techniques. Principle 9 of the Report states that:

"No profit shall be allowed for donations of ova, sperm, embryos or any element collected from them. Only loss of earnings as well as travelling and other expenses directly caused by the donation may be refunded to the donor."

3.7 This Report has not been formally adopted by the Parliamentary Assembly or the Committee of Ministers of the Council of Europe. However, a Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine was formally adopted by the European Council of Ministers in November 1996 and open to signature on 4 April 1997. At Article 21 the Convention states, "The human body and its parts shall not, as such, give rise to financial gain". An explanatory note gives the following comments on this provision:

"the human body and its parts shall not, as such, give rise to financial gain. Under this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital....Further, this article does not prevent a person from whom an organ or tissue has been taken from receiving compensation which, while not constituting

¹⁷ Adair, V, and Purdie, A. Donor insemination programmes with personal donors: issues of secrecy, *Human Reproduction*. 1996; 11, 2558-2563.; 7, 121-127; Daniels, K R. Semen donors in New Zealand: their characteristics and attitudes. *Clin. Reprod. Fertil.* 1987; 5, 177-190.

¹⁸ Ad hoc Committee of Experts on progress in the bio-medical sciences, Report on human artificial procreation, .Council of Europe, 1989.

remuneration, compensates that person equitably for expenses incurred or loss of income (for example as result of hospitalisation)."

3.8 It is not yet known whether the United Kingdom will sign the Convention, and, if so, what implications this may have for the law in this country. However, the principle is clear, and, irrespective of whatever action is taken by the UK Government, there would appear to be a general movement away from payment within Europe¹⁹.

Conclusion

3.9 Many of the issues surrounding gamete donation are contingent on the existing sexual, economic and moral culture. However, a nation's culture can change, and this can be encouraged by addressing both the practice of donation and the associated attitudes and values held by patients, doctors and the public at large. Within Europe there is a move towards the position that payment is unacceptable. The HFEA's policy is consistent with this general trend.

¹⁹ Shenfield, F Vive la difference. Progress in Reproduction, 1997; Vol 1., Issue 2, pp 6-7.

A regional or national recruitment service?

4.1 A possible obstacle to culture change maybe the close association of the donation process with treatment services. Donation and treatment usually occur on the same premises with the same staff, and, in some cases, in privately funded treatment centres. In such circumstances withdrawal of payment might appear contradictory to potential donors who might believe that clinics were benefiting financially from their generosity or that the commercial environment in which they were making their donation was inconsistent with non-payment. In addition, although it is desirable to keep the processes of donation and treatment separate as far as possible, this is difficult to achieve in a clinic driven primarily by therapeutic considerations. The HFEA therefore considers that an institutional change in which donation was clearly separated from treatment might be helpful in implementing a system of non-payment. It proposes that serious consideration be given to the idea of establishing a national donor service (or several regional donor services) which would raise awareness of gamete donation and recruit donors. This suggestion has already received some support²⁰.

4.2 There appear to be a number of advantages to the setting up of such a service:

- health professionals working at regional/national centres specialising in donation would naturally develop a more donor-orientated approach;
- cultural change could be facilitated;
- a central educational/training programme could replace those at centres currently recruiting donors;
- a more cost effective means of providing the best and most up-to-date technology in screening and storing gametes could be offered and research would be facilitated;
- the regulation of the number of children born per donor would be easier;
- the risks of consanguinity could be reduced because a national centre could ensure that a donor was used in more than one geographical area;
- consistency in data collection would be enhanced;
- donor recruitment would be removed from the predominantly commercial environment in which treatment is offered. This might make advertising more acceptable;
- the provision of counselling specifically for donors could be facilitated;

²⁰ Abdalla, H I, op. cit., (14).

- the efficient use of the supply of donors could be maximised; and
- the matching of patients from ethnic minority groups with donors could be improved because of access to a wider pool of donated material.

4.3 The HFEA has also identified some disadvantages of having a national recruitment agency including:

- that donors might have to travel further;
- the loss of control by individual clinics over their own recruitment process; and
- starting up costs.

4.4 The HFEA supports the creation of a regional or national donor service believing that this would be a significant step towards addressing the concerns identified in this paper. Such a service could provide a co-ordinated approach to the development of recruitment methods and would help to maximise the efficient supply of donors. It would also be a good source of information about donor recruitment. The HFEA believes that the service should be run on a non-profit basis ensuring that the charge per straw covered running costs. The biggest practical hurdle would be the start-up costs. While recognising that the HFEA is not set up to run such a body, it has considered four possible models on which such an organisation might be based being:

- an existing national organisation;
- a trade organisation based on subscription fees from the clinics;
- an organisation led by patient or professional groups; or
- a public body administered by the Department of Health.

Alternative recruitment methods - identifying potential donors

4.5 The HFEA is aware that several clinics have been actively working to attract unpaid donors. While the HFEA does not have a recruitment role, it knows of the difficulties clinics face in this regard. This section presents a number of recruitment methods which have been brought to the HFEA's attention.

4.6 Based on what was said earlier (see paragraph 2.2), it is reasonable to assume that, in respect of sperm donors at least, the profile of unpaid donors will probably differ from that of present paid donors. It is likely they will be older and have a family. As also previously indicated, where egg donors are concerned the issue is about increasing the current supply rather than targeting other groups of women. Although the challenges seem different, in future both sperm and egg donor recruitment will require much clearer identification of those

types of persons who are likely to become donors and then precise, targeted efforts to communicate effectively with them.

Pilot Studies

4.7 Although clinics believe that pilot studies are necessary for any successful implementation of the HFEA's policy, there are difficulties in carrying out such studies. For example, there would be a problem recruiting paid and unpaid donors in parallel, and the attitudes of many clinic staff towards non-payment might influence the results. For these reasons the HFEA has concluded that pilot studies are probably at present impracticable, although the introduction of a national or regional donor recruitment service might overcome these problems.

General recruitment approaches

4.8 Raising awareness of the need for donors may take place in a number of ways. For example through: advertising; articles in magazines/newspapers; television programmes; talks or speeches; word of mouth; and personal experience. What motivates individuals to take action is less clear, and some methods of raising awareness may be more effective than others depending on the circumstances.

Advertising

4.9 Advertisements may be placed by potential recipients, by clinics or by organisations not directly involved in treatment. Based on anecdotal evidence, advertisements placed by individual couples do appear to be successful in recruiting egg donors. However, although advertising by clinics is one way of raising awareness, it does not provide an easy mechanism for answering questions or giving more information, and this may limit its effectiveness. An advertisement is something which does not usually do more than act as a reminder or give very short-term pause for thought.

4.10 Further, advertising which is poorly conceived may do more damage than good, and some concerns expressed about advertising in relation to egg donation have already been mentioned (see paragraph 2.7). Advertising may be felt to "commercialise" donation - the very opposite to the change in culture which is desired. The fact that fertility treatment is often not NHS funded, or even based at an NHS hospital, means that advertising by clinics may reinforce the commercial environment in which donation is likely to take place. The HFEA believes that advertising can be a valuable tool, but it should be used cautiously.

Articles in magazines/newspapers and television programmes

4.11 The coverage given in the broadcast and print media on gamete donation is likely to be more informative than a paid advertisement. However, there is no control over when or where such coverage appears, who writes the articles or makes the programmes or what they say. Individual case histories can be particularly valuable in changing attitudes. However, care would have to be taken to protect patients. The HFEA has concluded that media coverage of gamete donation and treatment using donated gametes may be helpful, but would need to be carefully co-ordinated. A national or regional donation service would be well placed to do this.

Talks or speeches

4.12 Informal talks, formal speeches or seminars by informed individuals are an effective method of initially raising awareness especially if directed at appropriate target audiences. This approach, backed up with literature or videos, allows potential donors time to consider the implications of donation and avoids the possible embarrassment of a direct appeal from one individual to another. The HFEA is aware through anecdotal evidence of this technique being used with some success to recruit egg donors.

Videos or tapes

4.13 Use of a video or tape by clinics or any other appropriate organisation could act as complementary material to talks or seminars, and might help raise awareness of donation.

Word of mouth

4.14 Sperm donors - Communication at an individual and personal level can be an extremely effective method of donor recruitment. It is one which is used with good results by some clinics already²¹. However, if the donor profile changes because of a move to a system of non-payment, this may become less effective.

4.15 As mentioned previously, students currently represent a good group from which to recruit donors. If a student is asked to consider letting his friends know about sperm donation, these men are not only in a similar position to himself, but are also probably physically close to that particular clinic. In future the unpaid potential donor may not be part of such a large homogenous group. Consequently he may be in contact with fewer people who are either likely to become donors or to be near the clinic at which he is donating.

²¹ Cook and Golombok, op. cit., (3).

4.16 The message that an unpaid sperm donor will be asked to pass on will be different too. At present, a sperm donor can present donation as a means of earning extra cash. This message is simple and easy to get over as it does not invite any consideration of the real issues involved. In future, if more emphasis is to be placed on the value of the donation rather than on payment, the message will be harder to get across and more time consuming. The HFEA assumes that sperm donors may be less likely to become involved in recruiting others after payments are withdrawn, although this effect may be reversible in the longer term.

4.17 Egg donors - In contrast with sperm donors, egg donors are more likely to remain good recruiters after payment is withdrawn. This is because, as was noted earlier (see paragraph 3.1), women are generally more comfortable when talking about reproductive issues and are already more altruistically motivated. The HFEA would encourage clinics to consider egg donors as potential recruiters. This further emphasises the need to ensure that donors feel valued and that they find their experience of donating worthwhile.

4.18 Rejected donors - Although rejected donors are unlikely to play an active role in recruiting donors, the HFEA recommends that attention be paid to ensuring that they are not made to feel that they have failed or are themselves in some way less than normal. Rejected donors form part of the general population and their attitudes and experiences will also affect the cultural values and perceptions of society generally.

4.19 Patients - The HFEA has concerns about the use of patients to recruit donors on a routine basis. There is a risk of adding to the stress and pressures that patients are already under when waiting for, or receiving, treatment. In particular, patients should not be offered any form of inducement or put under any kind of pressure to recruit donors, for example, by being offered treatment sooner ("queue jumping").

4.20 Relatives or friends of patients receiving treatment will often volunteer to donate. Provided suitable precautions are taken, this is an acceptable source of donated gametes. The known donor could, for example, be used anonymously in another patient's treatment. This system of pooling egg donors has been described as operating successfully²², and would appear to avoid the concerns that are commonly voiced over the use of known donors in treatment²³. These concerns mainly relate to the continuing relationship between the donor and the recipient after treatment and the effects that this may have on family relationships and on the resulting child's upbringing.

²² Weil, E, Cornet, D, Sibony, C, Mandelbaum, J and Salat-Baroux, J. Psychological aspects in anonymous and non-anonymous oocyte donation. *Human Reproduction*. 1994; **9**, 1344-1347.

²³ Franco, J G. Donor anonymity and donation between family members. *Human Reproduction*. 1995; **10**, 1333; Saunders, D M and Garner, F. Oocyte donation using 'known' donors: it may seem the convenient answer but who pays? *Human Reproduction*. 1996; **11**, 2356-2357; Schenker, J. Oocyte donation by a minor to her mother. *Human Reproduction*. 1995; **10**, 1332; Sureau, C and Shenfield, F. Oocyte donation by a daughter. *Human Reproduction*. 1995; **10**, 1334.

4.21 Staff at clinics - Staff at clinics should be encouraged to be aware of the impact they have both inside and outside the clinic. In particular, they can present a friendly and supportive environment for any potential donors approaching a clinic.

Personal experience

4.22 It has been suggested that previous patients may be a possible source of donors. They will have good knowledge about infertility and the implications of treatment. For example, recipients of DI may be asked to consider egg donation and the male partners of IVF patients may be asked to consider sperm donation. Anecdotal evidence suggests that this is a singularly unsuccessful method of recruitment, although it would be interesting to see whether independent research would support this.

4.23 Previous patients who have embryos in storage sometimes decide to donate those embryos to others. Embryo donation is relatively rare for the following reasons:

- the consents of both the man and woman must be compatible;
- as patients, the couple may be less likely to consider donation as an option; and
- the couple may not remain in contact with the clinic after their treatment has finished.

4.24 Nevertheless, embryo donation should not be overlooked. The HFEA recommends that clinics raise embryo donation as a possibility when carrying out their storage reviews with patients.

The HFEA's Role

4.25 As explained above, while it is not appropriate for the HFEA to become directly involved in recruiting donors, it sees itself, whenever possible, adopting a supporting role. This could be done, for example, through the HFEA's literature. Inspections could also prove supportive by giving greater priority to examining donor recruitment practices at clinics. The provision of guidance notes for inspectors would help to educate inspectors and the clinics being inspected. The HFEA is currently reviewing its literature and its Code of Practice with a view to giving greater emphasis to the needs of donors.

PART 5. EGG SHARING, DONATIONS MADE FOR OTHER BENEFITS-IN-KIND AND GAMETES DONATED FOR RESEARCH

"Paid" egg-sharing schemes

5.1 The proportion of egg donors recruited through "paid" egg-sharing schemes is increasing, although to what extent is unknown. While there is little published evidence about the attitudes of women who donate through such schemes, it is likely that the number of egg-sharers would decline sharply with a withdrawal of benefits-in-kind. The HFEA has come to this conclusion for two reasons:

- egg-sharers have agreed to donate on the basis that they receive treatment at a reduced cost; and
- if these patients can still afford treatment after benefits-in-kind are withdrawn, they are unlikely to share their eggs because they will wish to maximise the number of embryos that they have in storage for future treatments.

The above is supported in part by a published survey which demonstrated that, although egg-sharers may have altruistic motives, a majority also gave 'helping us to have a child' as a motivation for being an egg-sharer²⁴.

Unpaid egg-sharing

5.2 The HFEA considers that patients should still be able to donate if they wish during their treatment cycle provided no benefits are offered in exchange for the donation. The only women who are likely to remain egg-sharers are those who donate when they find their ovarian stimulation has resulted in a large number of eggs which they decide to share. These women, who account for a very small number of donations, receive no reduction in the cost of their treatment as a result of donating.

The HFEA's concerns about "paid" egg-sharing

5.3 The HFEA has serious concerns about "paid" egg-sharing chiefly because the value in money terms of the benefits that patients receive in exchange for donating their eggs is significantly more than the £15 payment currently allowed. The cost of one IVF cycle can be up to £2000 - 3000. This level of payment, whether the donor receives all or part of her treatment free, has greater potential to act as a financial inducement, and this in turn raises

²⁴ Ahuja, K A, Mostyn, B J and Simons, E G. Egg sharing and egg donation: attitudes of British egg donors and recipients. *Human Reproduction*. 1997; **12**, 2845 - 2852.

concerns about the quality of the consent given and its freedom from inducement and pressure. In addition, there are fears that the offer of treatment can act as an even stronger pressure than money because of the particular value that the treatment has for the patient.

5.4 It can be argued that these worries are countered by the benefit a patient-donor derives from the donation²⁵. A patient who shares her eggs would like to have a child and IVF treatment is her best chance of achieving that wish. However, the HFEA's concern is whether the sharing of that patient's eggs is an acceptable means of achieving that end. In comparison, would it be considered acceptable for patients to sell/donate their kidneys in order to pay for/receive IVF treatment?

5.5 Although a patient who shares her eggs may receive fertility treatment through an egg-sharing scheme, that treatment will be harmed by the very fact that she has donated. The most up-to-date data show that the mean live birth rate for women having stimulated IVF with their own eggs is 15.4%²⁶. If a patient is unsuccessful at her first attempt, which will probably be the case, the fact that she has donated half of her eggs reduces the number of embryos she will have in store for future treatments. In addition, she may still not be able to afford such treatments. In which case she will have to donate again in order to have access to treatment.

5.6 In contrast, the recipient's chances of success appear to be greater. The most recent data shows that the mean live birth rate for women receiving unstimulated IVF treatment with donated eggs was 19.7%²⁷. The same trend was also revealed in the results of a published study on egg sharing²⁸ which reported higher pregnancy and live birth rates for recipients than for donors even though the recipients were older. The reasons for this are unknown, although they may be related to the different causes of infertility in each category.

5.7 It has also been suggested that the system of egg-sharing avoids exposing a healthy non-patient to the process of ovarian stimulation²⁹. Ovarian stimulation carries the risk of Ovarian Hyperstimulation Syndrome (OHSS) and there maybe long term side effects. The patient-donor on the other hand must undergo ovarian stimulation as part of her treatment, and, therefore, it is suggested it is more reasonable for her to become a donor. However, there are concerns that a patient who egg-shares will be exposed to a greater physical risk as a result of donating. This is because she will have fewer embryos in cryo-storage as a result of donating some of her eggs and consequently may need to undergo ovarian stimulation more

²⁵ Ahuja, K K, and Simons, E G. op. cit., (15).

²⁶ HFEA, op. cit., (13).

²⁷ ibid

²⁸ Ahuja, K K, Simons, E G, Fiamanya, W, Dalton, M, Armar, N A, Kirkpatrick, P, Sharp, S, Arian-Schad, M, Seaton, A, and Watters, A J Egg-sharing in assisted conception: ethical and practical considerations. *Human Reproduction*. 1996; 11, 1126-1131.

²⁹ Ahuja and Simons, op. cit., (15).

often. In addition, if the risks associated with stimulatory drugs are so great as to make their use unethical on non-patients, is it acceptable to continue their use in treatment?

5.8 The HFEA has only been able to identify one possible risk to the egg-sharing recipient. This is that the treatment may be less successful if the recipient receives eggs from a woman of unproven fertility.

5.9 To summarise, the HFEA does not believe that the donation of gametes should be used as a means of gaining access to treatment. It is likely that the patient only donates in order to receive treatment. Even if inducement could be ruled out through counselling and the provision of appropriate information, the benefit of treatment which the donor receives may be harmed by the donation. The HFEA also has concerns about the longer term emotional and psychological stresses on a patient who has donated in such circumstances. The process of considering donation may place additional stresses on a patient at a time when she is considering her own treatment. The patient-donor may worry about the outcome for the recipient and whether or not she became pregnant. These concerns may increase if she fails to conceive and then must cope not only with being childless, but also with the possibility that another woman may be bringing up a child which is genetically hers.

Other types of benefits-in-kind

5.10 The HFEA has also considered what other benefits might be offered in exchange for donation. The only other forms of benefit of which it is aware are free or reduced cost sterilisation or hysterectomy in exchange for egg donation. The HFEA has concluded that the risk of financial or other inducement was greater for such patients than for non-patient donors as the value of the treatment in money or other terms would be greater than the £15 payment currently allowed. The HFEA understands that these recruitment methods are not widely used and their removal is unlikely to affect the supply of egg donors.

5.11 Benefits-in-kind do not appear to have been used to recruit sperm donors. This may be due in part to the fact that sperm donation is not an invasive procedure. Unlike egg donation there are no treatments which may be carried out at the same time as the donation is made. It may also be due to the fact that the supply of sperm donors generally meets demand in this country.

Gametes donated for research

5.12 As no human life will result from the donation of gametes for research purposes this is more akin to participation in medical trials or the donation of other body tissue for research. As a result, the arguments against paying donors who donate gametes for research are

different. However, the HFE Act allows donors to vary or withdraw their consent at any time. This means that there would be nothing to prevent a donor who had originally consented to the use of their gametes in research later varying their consent to include treatment. The HFEA has concluded that it would therefore be impossible to make a distinction between gametes which had been donated for research and paid for and gametes which had not.

5.13 The HFEA has also decided that the implementation of its policy might be harmed if some donors were paid and others not, whatever the intention behind the donation. In addition, there is a risk that the cultural change that the HFEA is trying to promote might be at odds with a policy of allowing payment for some donors.

PART 6 INTRODUCING AN EXPENSES ONLY SYSTEM

6.1 The HFEA has considered three different approaches to withdrawing payment: "wither on the vine"; a stepped removal of payment; and a sudden removal of payment.

"Wither on the vine"

6.2 The wither on the vine approach would involve fixing the amount of payment that is allowed under current Directions until the effect of inflation was to reduce its value to a negligible amount. The merit of such an approach is that it seemingly allows plenty of time for alternative recruitment strategies to be developed with the value of the payment decreasing naturally until its removal has little or no effect.

Multi stepped removal of payment

6.3 This approach would involve reducing the payment in stages. The most likely reductions would be in £5 "steps" producing a three stage process. This would also allow time for new recruitment schemes to be established, and would give more control to the HFEA in implementing its policy. The removal of some amount of payment is likely to act as a stimulus to clinics to make changes, and would, in addition, enable the HFEA to respond to clinics' successes in recruiting unpaid donors by increasing or decreasing the timescale, as necessary.

Single step removal of payment

6.4 A single step removal of payment would provide the cleanest transition from a system of payment to a system of non-payment. The advantages of this approach would be that the HFEA's policy could be implemented more quickly and that it would be easier to establish a new ethos surrounding gamete donation.

Discussion

6.5 The argument has been made by clinics for the removal of payments by a gradual and drawn out process. However, this would create a Catch 22 situation. As explained earlier, the recruitment of unpaid donors in satisfactory numbers is likely to require a change in society's perception of donation, in DI and in related cultural values. This will take time to achieve. However, if payments are allowed to continue, current values and attitudes are reinforced and change is slowed down. This dilemma was brought home to the HFEA when it considered the viability of running pilot studies. It is difficult to imagine how an unpaid donor

recruitment scheme could be run successfully in parallel with a paid control scheme because the unpaid donors would know about the paid donors. In this situation unpaid donors might either feel exploited because they were not being paid or that the nature of their gift was being harmed by the presence of paid donation in the same system. These concerns were highlighted by the controversy caused to the blood donation system in this country when an internal market was introduced. The perceived commercialisation of the system resulted in the loss of a number of donors, some of whom were protesting deliberately against the threat they perceived being posed to the nature of donation. It has been suggested that, where paid and unpaid donor recruitment systems operate together, it is the recruitment of unpaid donors that suffers³⁰. This favours a one step withdrawal of payment.

6.6 It is not just donors' attitudes towards donation that have to be taken into account, but also those working in clinics. The HFEA is concerned that, whatever timescale is agreed upon, clinics, professional and patient organisations should be encouraged to begin preparing for change now. If payment were not removed until some medium or long term date, there is a risk that little would be done in the meantime to change the culture of donation.

6.7 For the reasons explained above, the HFEA does not consider either a "wither on the vine" approach or the multi stepped removal of payment satisfactory. These could take a considerable time to achieve their end and would send a powerful message of "no change" thereby reinforcing current attitudes. The HFEA believes that the single step removal of payment is a more appropriate method of implementation especially if it was tied to the introduction of a clear and well regulated system of expenses that emphasised the importance of financial neutrality to the donor.

Expenses

6.8 The definition of expenses has been an issue which has been of particular concern to clinics. **The HFEA defines expenses as necessary and consequential costs incurred directly as a result of making the donation.** The HFEA wishes to make clear its view that donors should not have to carry any of the financial costs of gamete donation. Further, expenses should be reimbursed for each visit to a clinic rather than for each donation as this breaks the link between payment and the provision of gametes.

6.9 The HFEA prefers the system of payment of expenses described above to the usual current practice of making a fixed expenses payment, the amount varying with clinics. Of course, receipts or a similar proof of costs incurred should ideally be produced. Having said that, the HFEA recognises that there are a number of difficulties with this, not least that it

³⁰ Dickenson, D. Procuring gametes for research and therapy: the argument for unisex altruism - a response to Donald Evans. *J. Med. Ethics.* 1997; 23, 93-95.

would prove difficult and expensive for clinics to administer. It might also disadvantage those donors with low costs, such as bus fares, which could not be claimed if tickets were lost. The HFEA therefore proposes that receipts below a certain limit should not be required.

Compensation for loss of earnings

6.10 The HFEA opposes the reimbursement of loss of earnings on the grounds that it would place a different value on gametes based purely on the donor's occupations. Further, the decision to donate is made by the donor as a private individual, and not in their paid role as a builder, student, teacher or whatever. The HFEA also has concerns that gamete donation should not be seen as in any way equivalent to a paid occupation. Such a concern has also led the HFEA to reject the idea of a standard hourly rate independent of the donor's employment.

RESPONDING TO THIS CONSULTATION

This document has explained the HFEA's position. Consultees are invited to complete and return the enclosed Questionnaire explaining their views and concerns. This should be sent to:

Beatrice Heales
c/o HFEA
Paxton House
30 Artillery Lane
London, E1 7LS

The Questionnaire should be returned by no later than 31 July 1998.

QUESTIONS

This is a copy of the questions to be found in the enclosed questionnaire which you are asked to complete and return to the HFEA.

A. The Payment of Expenses (see paragraphs 6.8-6.10)

The HFEA defines expenses as necessary and consequential costs incurred directly as a result of making the donation.

Q1.	Should expenses be reimbursed?	yes/no
Q2	If yes, then what expenses should be allowed and for what amount, e.g.:	
	travel to and from the centre for each separate visit	yes/no
	up to £10	yes/no
	up to £15	yes/no
	more than £15	yes/no
	if more than £15, what should the ceiling be	£.....
	child care costs	yes/no
	up to £10	yes/no
	up to £15	yes/no
	more than £15	yes/no
	if more than £15, what should the ceiling be	£.....
	subsistence (food & drink consumed away from home)	yes/no
	up to £10	yes/no
	up to £15	yes/no
	more than £15	yes/no
	if more than £15, what should the ceiling be	£.....
	other expenses	yes/no
	If yes, please list and give the ceiling figure	
Q3	Should receipts always have to be produced	yes/no
Q4	If no, should expenses be paid without receipts being produced for:	
	up to £10 in total	yes/no
	up to £15 in total	yes/no
	more than £15 in total	yes/no
	if more than £15, what should the ceiling be	£.....

B. Timescale for Introducing an Expenses Only System (see paragraphs 6.1-6.7)

Q5 Should an expenses only system be introduced in a single step? yes/no

Q6 Should the expenses only system be introduced by multi stages? yes/no

If yes, please give your reasons why.

O7 What do you think should be the target date for introducing a non-payment system:

a) if introduced in a single step?

1 January 2000	yes/no
1 January 2001	yes/no
1 January 2003	yes/no
some other date	yes/no
if yes, the date should be

b) if introduced in phases?

to start immediately	yes/no
to start in 1998	yes/no
to start in 1999	yes/no
to start in 2000	yes/no
to be completed in 1999	yes/no
to be completed in 2000	yes/no
to be completed in 2001	yes/no

Q8 Should a "wither on the vine" approach be adopted? yes/no

If yes, please give your reasons why.

C. Benefits-in-Kind:

Paid Egg-sharing Schemes (5.1, 5.3-5.9)

Q9 Should paid egg-sharing schemes be allowed to continue? yes/no

Please give reasons for your answer.

Q10 If not, should such schemes be ended immediately? yes/no
or
be phased out over time yes/no

Q11	If you feel that such schemes should be phased out over time, then should this be done?	
	by 1999	yes/no
	by 2000	yes/no
	by 2001	yes/no
	sometime later	yes/no
	if sometime later, give the end date
Other Benefits-in-Kind (see paragraphs 5.10-5.11)		
Q12	Should other schemes based on benefits-in-kind continue?	yes/no
Q13	If not, should such schemes be ended immediately? or phased out over time?	yes/no yes/no
Q14	If you feel that such schemes should be phased out over time, then should such schemes be completed by:	
	by 1999?	yes/no
	by 2000?	yes/no
	by 2001?	yes/no
	sometime later	yes/no
	if sometime later, please give the end date
C. Gametes Donated for Research (see paragraphs 5.12-5.13)		
Q15	Should payment for gametes donated for research continue after payment to donors ends?	yes/no
D. A National Donor Service (see paragraphs 4.1-4.4)		
Q16	Would you be in favour of a national donor service being established?	yes/no
Q17	If yes, do you think such a service should:	
	campaign to recruit more egg donors?	yes/no
	campaign to recruit more sperm donors?	yes/no
	give information about where to donate?	yes/no
	provide a complete recruitment, banking and supply service for donor sperm?	yes/no
	recruit and counsel egg donors and liaise with clinics where donation would take place?	yes/no
	eventually store and supply eggs as techniques allow this?	yes/no

E. Research

The HFEA would welcome comments on what research needs to be done and how such research might be taken forward. Please note that the HFEA is not able to fund such research itself.

Further Comments

The HFEA is interested in receiving any general comments you may wish to make. It would particularly welcome comments on the following:

- what could be done generally to encourage recruitment of unpaid sperm and egg donation;
- details of what clinics propose to do or are doing now to recruit unpaid donors;
- whether embryo donation should be encouraged, and, if so, how to encourage more potential donors and recipients to consider it;
- how a national or regional donor service might be implemented.

ANNEX A

SOME INTERNATIONAL COMPARISONS

AMERICA

The American Fertility Society's guidelines¹ make the following recommendations on payments to egg and sperm donors:

Egg donors

- A. "Donors should be compensated for the direct and indirect expenses associated with their participation, their inconvenience and time, and to some degree for the risk and discomfort undertaken."
- B. Financial obligations and responsibilities in the event of unanticipated complications or medical expenses of a donor should be contractually agreed upon prior to initiation of a stimulation cycle.
- C. Financial payments should not be so excessive as to constitute undue inducement.
- D. Payment is contingent upon participation in the program and may be prorated based on the number of steps completed in the procedure.
- E. In any event, payment should not be predicted on the number of oocytes obtained."

Sperm donors

"Payment to donors will vary from area to area but should not be such that the monetary incentive is the primary factor in donating sperm. However, the donor should be compensated for his time and expenses."

AUSTRALIA

Egg and sperm donors are compensated for their expenses although the amount paid varies from clinic to clinic². The Australian National Health and Medical Research Council published 'Ethical guidelines on assisted reproductive technology' in 1996 which stated that commercial trading in gametes or embryos was unacceptable³.

¹ American Fertility Society. Guidelines for gamete donation: 1993. *Fertility and Sterility* 1993; Vol. 59, No. 2, Supplement 1.

² Handelsman, D J, Dunn, S M, Conway, A J, Boylan, L M, and Jansen, R P S (1985) Psychological and attitudinal profiles in donors for artificial insemination. *Fertil. Steril.*, 43, 95-101; Daniels, K R (1989) Semen donors: their motivations and attitudes to their offspring. *J. Reprod. Infant Psych.*, 7, 121-127; Private communications.

³ National Health and Medical Research Council, Ethical guidelines on assisted reproductive technology, Commonwealth of Australia, 1996, p 15.

BELGIUM

There is no legislation in Belgium covering payments to gamete donors but the Free Universities allow compensation of around £20 to £30 for each sperm donation⁴.

CANADA

“Proceed with Care” the final report of the Royal Commission on New Reproductive Technologies gives comprehensive consideration of the issue of gamete donation. The following are extracts:

- No profit should be made from the selling of any reproductive material, including eggs, sperm, or zygotes/embryos, because of its ultimately dehumanizing effects.
- Because donors must spend considerable time a medical history, having a physical examination and coming back for repeated blood tests, and giving sperm samples, the Commission feels it is reasonable to compensate donors for their time and inconvenience.....Most sperm donors in Canada receive money intended to reimburse their out-of-pocket expenses - currently around \$75 (=£37) per donation. This is unlikely to act as a financial inducement, given the inconvenience involved, but we believe this level should not increase except perhaps to maintain its value relative to inflation.
- Eggs for donation be obtained only from women already undergoing surgical procedures or egg retrieval as part of their own treatment. Egg retrieval exclusively for purposes of donation should not be permissible.
- Designated donation of eggs to a named recipient not to be permissible.
- Payment for egg donation not be permissible.⁵

Since this report no new legislation has been passed although in 1996 Federal legislation was proposed which would have banned all payments to gamete donors.

FRANCE

The 1994 French Bioethics law (ART L 665-13) does not allow any payment of donors. CECOS which recruits most donors in France had been following a policy of non-payment since the 1970s⁶.

⁴ Shenfield, F. *Vive la difference*. *Progress in Reproduction*. 1997; Vol. 1, Issue 2, pp 6-7.

⁵ Royal Commission on New Reproductive Technologies. *Proceed with Care*; Final report of the Royal Commission on New Reproductive Technologies. Vol. 1; p.447-594

⁶ Jouannet, P. *Patients doing it for themselves*. *Progress in Reproduction* 1997; Vol. 1, Issue 2, pp 8-9.

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